i-limb™ digits
Clinician Manual

touch bionics

Part number: MA01064: Issue No. 2, December 2014

i-limb™ digits

This document provides instruction for prosthetists in the fitting and servicing of i-limb digits and should be read in full prior to fitting. It is highly recommended that the use of this manual is made in conjunction with instruction from a clinician experienced in the use of i-limb digits.

This symbol signifies important information and is used throughout the manual.

Refer to www.touchbionics.com/downloads/document-library to ensure you have the latest copy of this document.

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1.0 i-limb digits

1.1 Product Description

i-limb digits is a highly individualized, externally powered, multi-articulating prosthetic device offering functional enhancement of the partial hand.

Individually motorized digits work in conjunction with available anatomy to improve functionality. i-limb digits is externally powered and offers compliant grip through individually powered digits with stall out ability. A manually rotating thumb, when required, in conjunction with vari-grip, auto-grasp and the wide range of automated grip patterns lead to broad functionality.

Users can choose from a wide selection of automated grips and gestures to help complete daily tasks, depending on i-limb digits configuration. Grips and gestures can be customized further for precise control.

The Wristband design enables the range of movement at the wrist to be retained, while providing an open forearm to reduce the build-up of heat and associated sweating. Hand control sites provide a reliable electrode position facilitating the Wristband option.

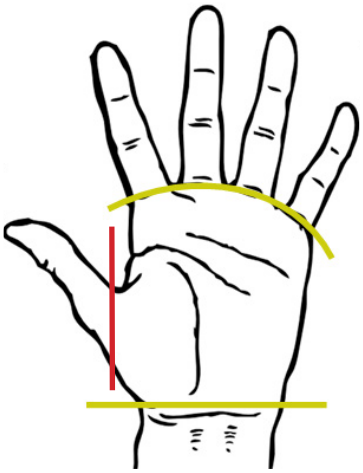
1.2 Intended Use

i-limb digits is intended to be used by patients with partial hand loss or deficiency.

1.3 Patient Selection

i-limb digits is appropriate for patients with partial hand loss or deficiency; where the level of loss or deficiency is:

- Distal to the wrist
- Proximal of the metacarpo-phalangeal joint



Devices are suited to patients with any 3, 4 or 5 digit loss, while patients with 1 or 2 digit loss are also indicated when the digits of loss are either the thumb or the main digits of opposition, namely the index and middle fingers. (i-limb digits devices have been used successfully outside of the above guidance).

i-limb digits is not indicated for patients with:

- insufficient hand loss or deficiency, as outlined above
- cognitive impairment, such that the device is unable to be controlled
- where skin integrity is insufficient to support a prosthetic device

1.4 Fitting Process

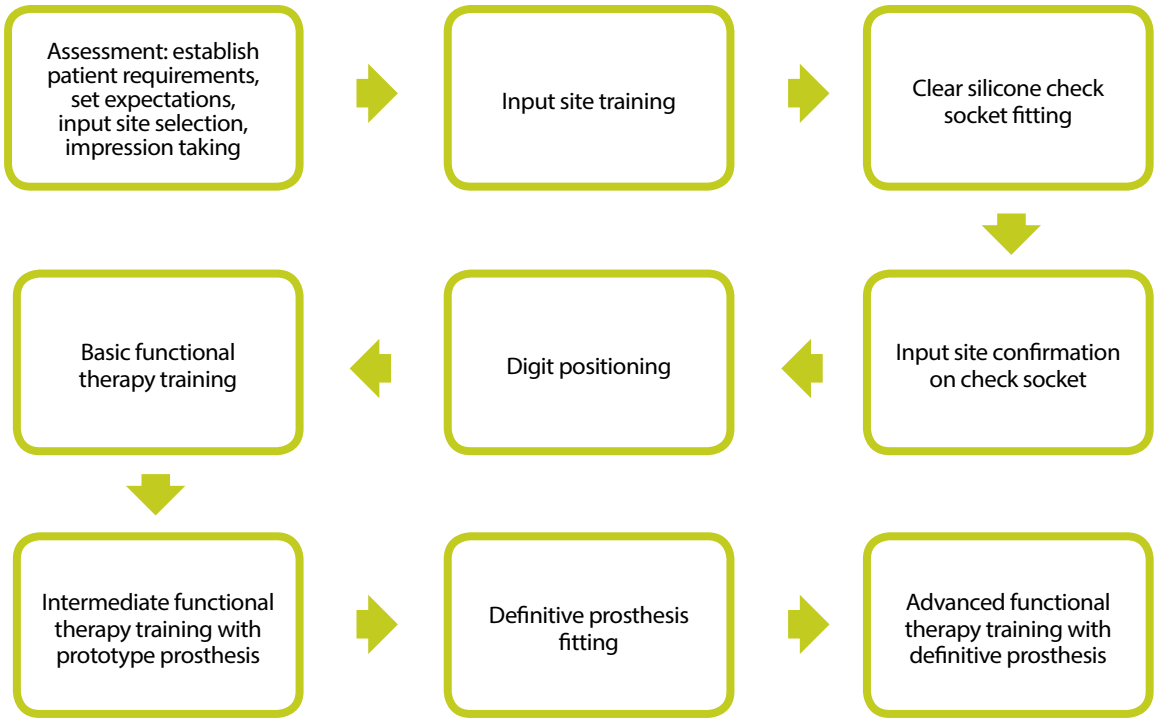
During the patient assessment stage consideration should be given to socket design. Standard prosthetic fitting factors including skin/socket interface, suspension of the prosthesis and donning/doffing, must be considered. Additional factors specific to i-limb digits include control site location and digit positioning.

After possible control sites have been identified and the most appropriate sites selected, an impression of the patients' residual limb can be taken. Initial control site training can commence prior to fitting of the check socket. The check socket should be assessed for fit, comfort, suspension and ease of donning/doffing. Appropriate location of electrode or FSR contacts should be determined. Any necessary alterations should be made prior to progressing.

Digit positioning takes place on the check socket to create a prototype prosthesis. During digit positioning a range of sizes and shapes of objects can be used to assess the optimal position with particular attention to opposition of digits, span of opening and coordination with any other remaining fingers.

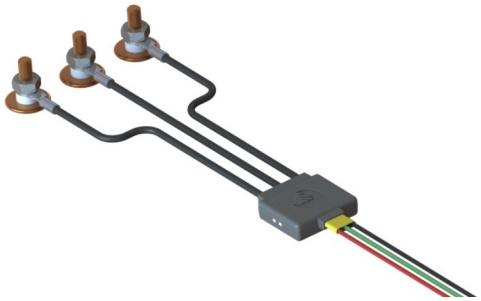
Basic Functional Therapy Training is carried out. During this stage the prosthetist should determine that the prototype prosthesis is optimized throughout a range of patient activities and ADLs. Any necessary changes should be made. biosim can be used throughout the fitting process to individualize the device. The definitive prosthesis fabrication can commence when the optimal prototype device has been achieved.

Intermediate Functional Therapy Training continues, again using the prototype device. At this stage biosim can be used to individualize the device. Once fabricated, the definitive socket can be tested for fit and function. Advanced Functional Therapy Training continues with the patient now using the i-limb digits prosthesis in real life situations.


Assessment: establish patient requirements, set expectations, input site selection, impression taking
Input site training
Clear silicone check socket fitting
Input site confirmation on check socket
Digit positioning
Basic functional therapy training
Intermediate functional therapy training with prototype prosthesis
Definitive prosthesis fitting
Advanced functional therapy training with definitive prosthesis

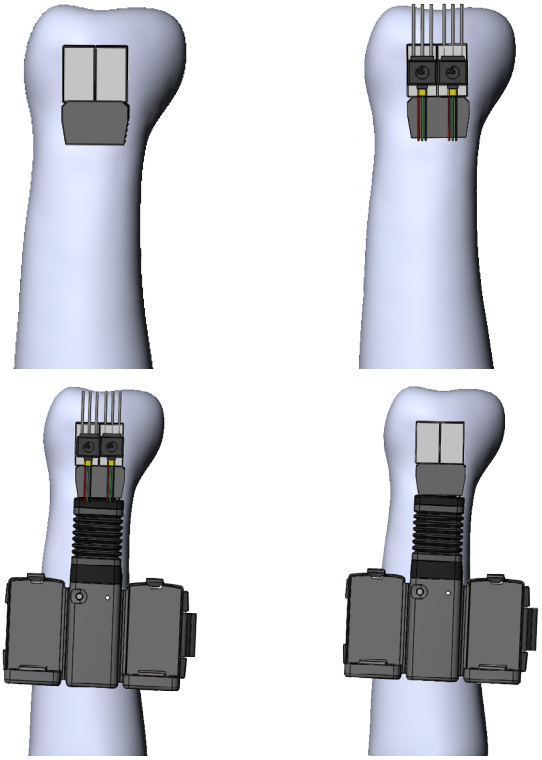
1.5 Control Site Options

i-limb digits devices are controlled by using either Remote Electrodes, FSR's (Force Sensing Resistors) as illustrated, or Standard Electrodes. Electrodes and FSR's are positioned within the socket. Review i-limb digits Component Assembly Guide (MA01073) for more information on assembly and fabrication.



Do not rely on previous myo-electrical testing.

Use anatomical sites where the electrode will maintain constant, even contact with the skin. Avoid placing electrodes near socket interface trimlines, bony areas, skin grafts or fatty tissue.

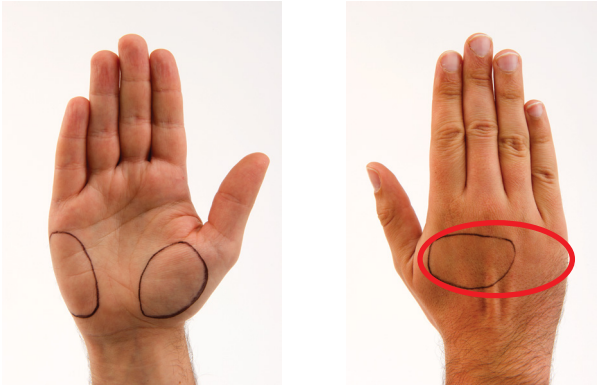


Electrode Site Selection

The three regions within within the hand are:

1. Hypothenar compartment
2. Thenar compartment
3. Dorsum of the hand

Consult section 3.3.1 for information on myo-testing within biosim.



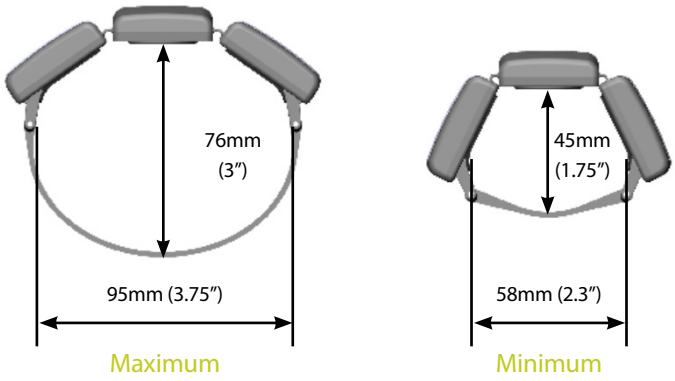
2.0 Wristband and Batteries

2.1 Wristband

The i-limb digits Wristband has a circumference range of 155mm (6″) to 270mm (10.5″) and is positioned approximately 50mm (2″) proximal of the wrist joint, depending on anatomy. If a larger Wristband is required, an extension piece can be added (contact Touch Bionics to discuss your needs).

The i-limb digits Wristband contains the PCB and two removable 3.7V batteries. It is connected to the socket and frame by a flexible sheath containing the wiring.

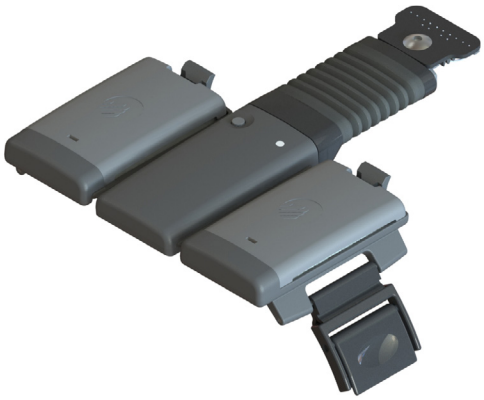
The wristband is designed to fit loosely around the distal forearm. It is not designed to be used for suspension of the prosthesis or to hold electrodes in position against the skin.



2.2 Battery

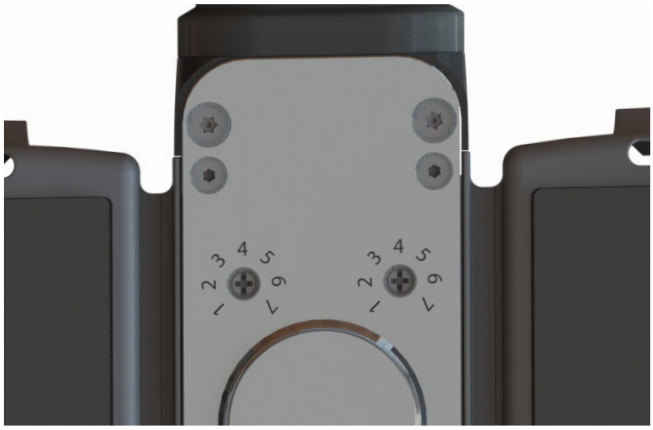
i-limb digits is powered by 2, 800mAh, 3.7 Volt batteries which have been specifically designed to meet the power requirements of i-limb digits devices. Four batteries are provided, two for the wristband and two spares. Two 3.7v batteries will be needed with the Wristband (the wristband will not work with only one battery)

Each battery is equipped with a LED display alerting you when the battery is low on charge. If the battery is low on charge the LED will illuminate RED. The LED will remain illuminated until the battery is adequately charged.



The Wristband is switched on and off via the grey button on the central panel. The light sequence is as follows:
On : Red light appears for 8 seconds
Off : Red light briefly flashes

On the underside of the wristband you are able to adjust electrode gains.



Batteries are fitted into the Wristband battery housing and secured by the holding catch at the wrist side of the Wristband. Release the holding catch to remove the battery.

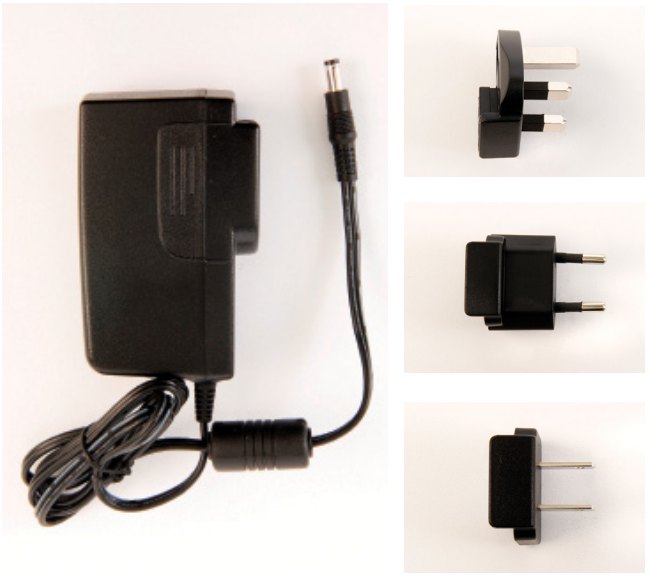
The batteries provided are designed to work specifically with the Touch Bionics i-limb digits Wristband and are not to be used with any other device.

Only Touch Bionics batteries are approved for use with i-limb digits, use of alternative batteries will invalidate the warranty.

2.3 Battery Charging

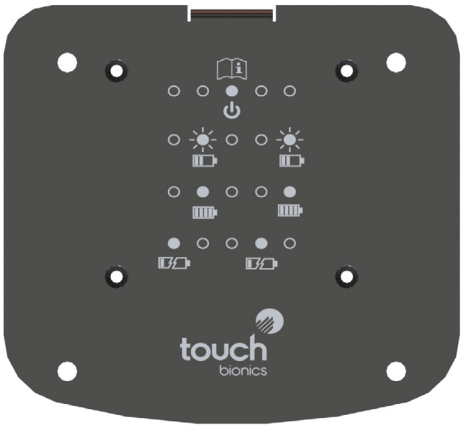
Batteries for i-limb digits should only be charged using the Touch Bionics powerpack and battery charger supplied. Place the batteries in the charger as illustrated. Insert the charger lead from the battery powerpack into the charge port. Insert the charger into the power outlet.

Charging time from full discharge is approximately 2 hours.



On the base plate of the charger you will see the various light sequences:

- Middle light on: Charger is plugged in
- 2nd and 5th lights blinking Green: Batteries are charging
- 2nd and 5th lights solid Green: Batteries are charged
- 1st and 4th Red lights on: Battery fault, unplug and try again. If lights continue to illuminate, contact Touch Bionics Customer Support.



Only use the plug to disconnect the charger, never pull the cable to remove the lead.

As an alternative to your patients charging directly from domestic power, a car charger is provided with the i-limb digits.

2.4 Storage and Maintenance

Always turn off the i-limb digits device when not in use.

Aim to charge the battery each day after use.

Replace the batteries every 12 months.

3.0 biosim

3.1 biosim Overview

All i-limb devices are fitted with a Bluetooth® receiver enabling it to work with a sophisticated software package known as biosim. biosim-pro is the clinician's version of biosim and biosim-i is the version designed for patient users. Using biosim, clinicians are able to make changes to the functionality of the i-limb device. biosim-i is the simplified patient user version of biosim and contains access to training and games features along with some basic changes to settings.

For clinicians to access and operate the biosim mobile application with the i-limb device, your will need to download the biosim application (downloadable from the Apple® App Store) to the iPod® Touch supplied by Touch Bionics or compatible device: iPhone® (4s or newer), iPad® (4th generation or newer), iPad® mini, iPod (5 or newer). Users of the mobile application can consult the Quick Start Guide available at www.touchbionics.com/downloads/document-library.

The biosim software, working through the Bluetooth "biosim handshake" wireless connection (not supplied, must be ordered), provides access to a range of control options, training features, real time display of impulses, battery status and health check.

While working with the patient user, an assessment should be made of their suitability to work with biosim-i. Patient users must understand and be comfortable working with the technology, to be able to make appropriate adjustments.

PC requirements are as follows: Window XP, Windows Vista, Windows 7, or Windows 8; Microsoft.NET framework v3.5; USB port for Bluetooth® connector. Mac requirements are as follows: Mac OS X Lion (10.7) and higher, USB port for Bluetooth connector. Occasionally updates to the biosim software and application will be available. Your computer will need to have an internet connection to recieve these updates. An automated notification will advise you when this is needed. Follow the steps as advised in the notification.

3.2 biosim Connecting

biosim is not contained on the bluetooth handshake device and must be downloaded from the internet. biosim can be found at http://www.touchbionics.com/biosimdownload. After downloading, open biosim by clicking on the biosim icon (fig. 1) which should be clearly visible on the screen. The biosim Handshake device (available for order, fig. 2) must also be inserted into a USB port to allow the Bluetooth signal to be received by the i-limb device. The Handshake Bluetooth receiver will pick up signals within a 10 meter range.

Figure 1

Figure 2

The opening welcome screen will load. The language can now be changed from the default English to a variety of languages. This is done by clicking on the language indicator at the bottom right hand side of the screen and scrolling to the required language. The first numerical icon "insert handshake" request will flash. On insertion of the handshake the icon will be constantly lit, the "handshake installed and ready" box will then self-tick. The second icon will now be constantly lit and the third icon "Connecting to device" will flash. The tab marked "connect" must now be clicked for the connection to be made, this will take approximately 15 seconds.

Welcome to biosim-pro
Follow these three easy steps to connect with a device
Insert handshake
Handshake installed and ready?
No
Turn device off, then back on
Connect to device
Connect
You can also choose one of the options below
Review offline patient information
Visit us on the web

If there is more than one i-limb device within range of the Bluetooth receiver then a box will appear listing all devices by serial number. Select the correct i-limb device from the list. The i-limb device serial number is located under the battery on the wrist band (fig. 3).

Figure 3

On opening biosim and linking to the i-limb digits device for the first time a response box will appear on the opening page requesting to run the configuration wizard (1). The configuration wizard allows the software to learn the wiring order for the digits and will follow the sequence outlined below.

Follow the prompts (2) and then input the digit size for each digit in turn (3). The drop down box will also allow a "not present" selection, indicating where the patient has an intact finger rather than mechanical digit.

The size can be found on the base of the digit. Once the information has been input the software will guide the user to the Digit Mapping screen (4). On starting the routine the user is prompted to enter which digit moves in turn as the software works through each of the digits (5).

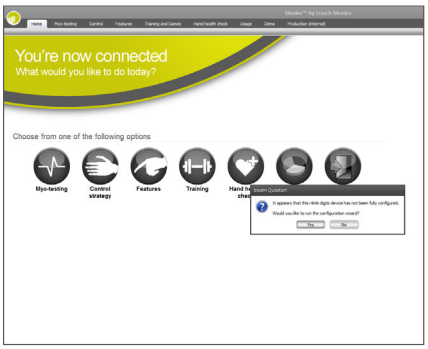
The user will be prompted after each digit moves during the mapping process, requiring the user to indicate if the digit was left in the open position (yes or no) (6).

On completion of the digit mapping the wizard will request input types for each channel (7).

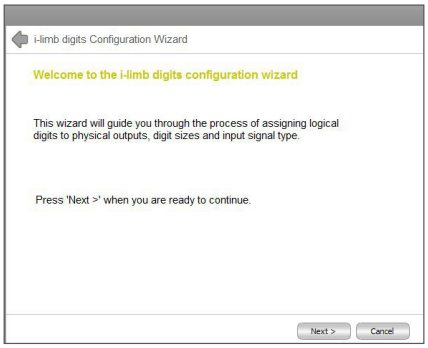
The wizard is then complete (8).

The Digit Configuration Wizard can be revisited at any time from the Control Strategy screen, via the i-limb digits tab on the right hand side of the screen (9).

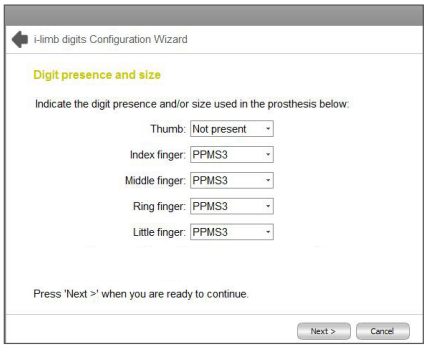
1



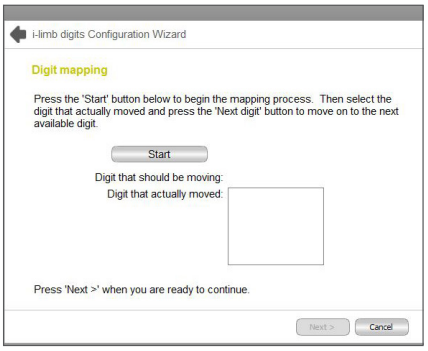
2


i-limb digits Configuration Wizard
Welcome to the i-limb digits configuration wizard
This wizard will guide you through the process of assigning logical digits to physical outputs, digit sizes and input signal type.
Press 'Next >' when you are ready to continue.
Next >
Cancel

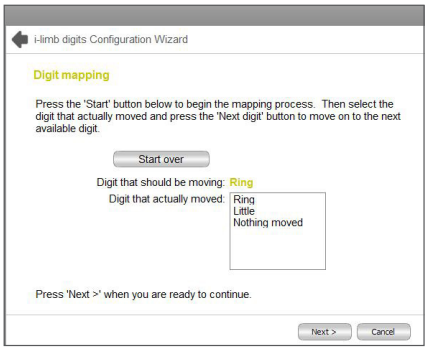
3


i-limb digits Configuration Wizard
Digit presence and size
Indicate the digit presence and/or size used in the prosthesis below:
Thumb: Not present
Index finger: PPMS3
Middle finger: PPMS3
Ring finger: PPMS3
Little finger: PPMS3
Press 'Next >' when you are ready to continue.
Next >
Cancel

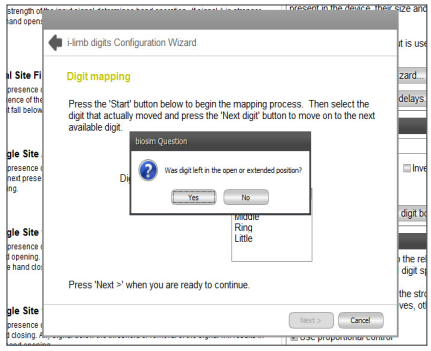
4


i-limb digits Configuration Wizard
Digit mapping
Press the 'Start' button below to begin the mapping process. Then select the digit that actually moved and press the 'Next digit' button to move on to the next available digit.
Start
Digit that should be moving:
Digit that actually moved:
Press 'Next >' when you are ready to continue.
Next >
Cancel

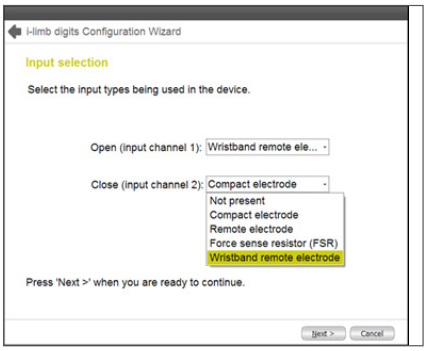
5


i-limb digits Configuration Wizard
Digit mapping
Press the 'Start' button below to begin the mapping process. Then select the digit that actually moved and press the 'Next digit' button to move on to the next available digit.
Start over
Digit that should be moving: Ring
Digit that actually moved:
Ring
Little
Nothing moved
Press 'Next >' when you are ready to continue.
Next >
Cancel

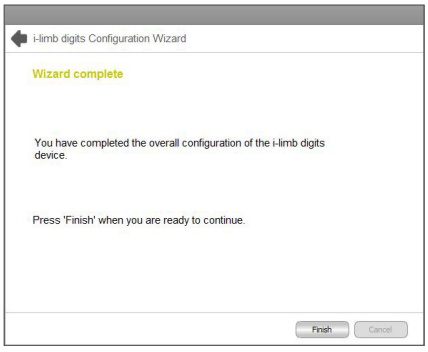
6


i-limb digits Configuration Wizard
Digit mapping
Press the 'Start' button below to begin the mapping process. Then select the digit that actually moved and press the 'Next digit' button to move on to the next available digit.
biosim Question
Was digit left in the open or extended position?
Yes
No
Ring
Little
Press 'Next >' when you are ready to continue.

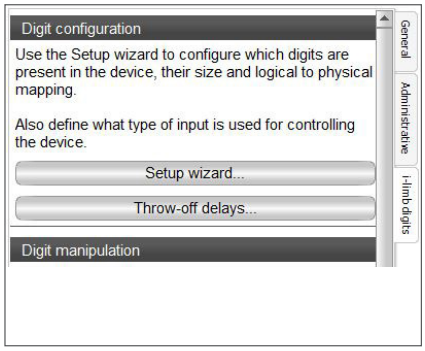
7


i-limb digits Configuration Wizard
Input selection
Select the input types being used in the device.
Open (input channel 1): Wristband remote ele...
Close (input channel 2): Compact electrode
Not present
Compact electrode
Remote electrode
Force sense resistor (FSR)
Wristband remote electrode
Press 'Next >' when you are ready to continue.
Next >
Cancel

8


i-limb digits Configuration Wizard
Wizard complete
You have completed the overall configuration of the i-limb digits device.
Press 'Finish' when you are ready to continue.
Finish
Cancel

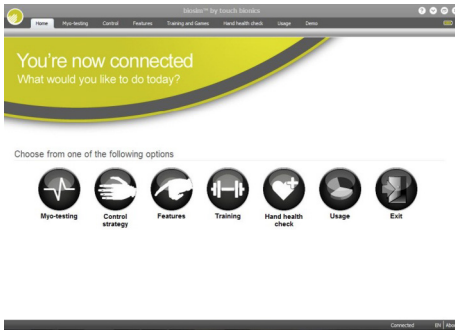
9


Digit configuration
Use the Setup wizard to configure which digits are present in the device, their size and logical to physical mapping.
Also define what type of input is used for controlling the device.
Setup wizard...
Throw-off delays...
Digit manipulation
General
Administrative
i-limb digits

3.3 Navigating biosim

The "You're now connected" home screen will now be displayed, with seven options as illustrated (fig.4). This is the homepage and can be accessed at any time from subsequent pages.

Figure 4



Myo-testing icon provides a quick and easy control site test along with a more detailed analysis screen.

Control strategy details the choice and information around the range of control options as well the logging of user information.

Features allows the set-up of the i-limb digits and is where triggers are linked with with grip patterns and gestures.

Training provides access to the training suite and a selection of games to improve overall control.

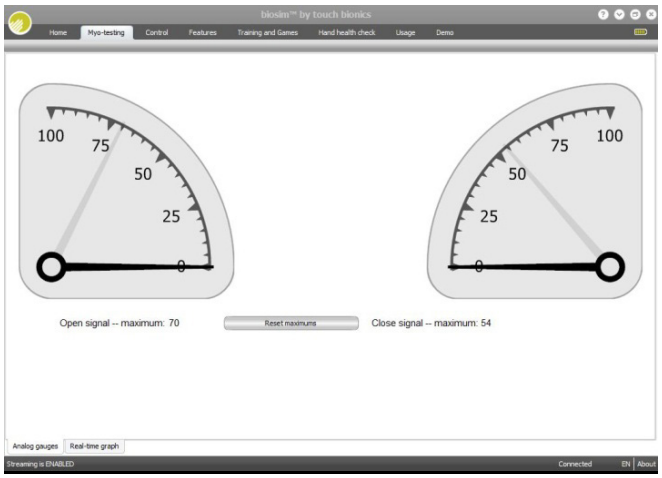
Hand health check icon provides a quick and easy diagnostic check of the hand.

Usage icon provides access to a tally of individual movements with additional analysis.

Exit icon draws the session to a close, exiting the program.

3.3.1 Myo-testing

The Analog gauges opening myo-testing screen provides a very quick and easy method of testing control site activation. The strength of open and closed signals will be illustrated on the gauges – the maximum reading will be left as a shadow on the gauge and the actual figure is provided below each scale.



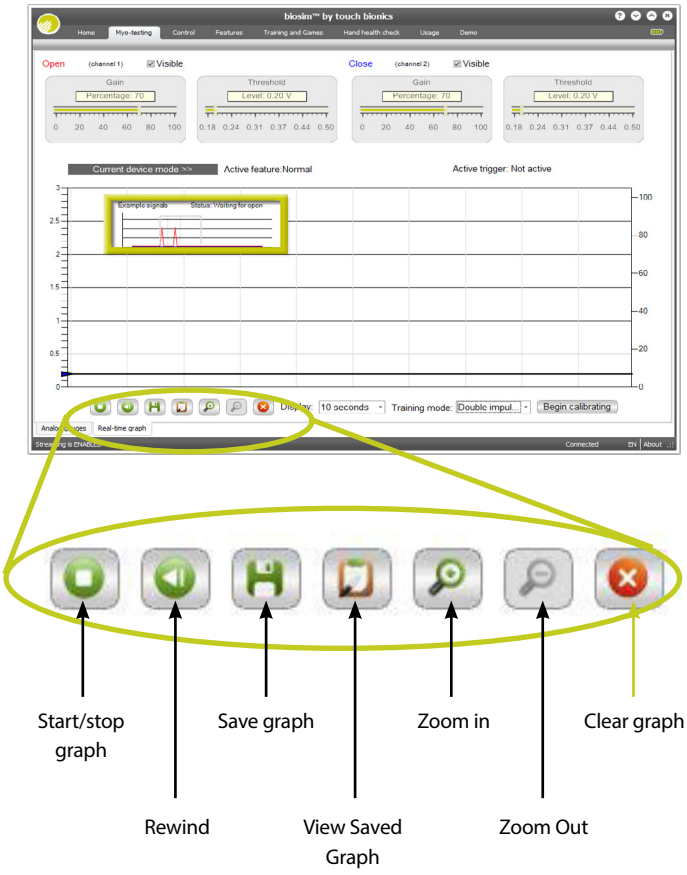
The Real-time graph screen plots a graph of the signal in real-time, with open signals in red and closed signals in blue. The choice of either open or closed input channels is offered, providing the option to make the signal curve invisible by unticking the Visible box at the top left of the screen.

Gain and Threshold levels are indicated, pre-set values being 70% for gain and a threshold level of 0.2V. Either can be modified depending on the needs of the user. On changing the threshold levels at the top of the screen the level is automatically changed on the graph.

The graph can be paused, restarted, saved or enlarged using the control at the bottom of the screen.

The graph automatically moves at a pace of 10 seconds per page, however can be altered to a speed of between 2 and 60 seconds per page.

Training mode option enables training with specific triggers.



i-limb digits is optimized for use with electrodes where the signal reaches between the 1.5 and 2.5 area of the graph with good differentiation between signals. If the gains are set to their maximum or minimum, then the user may find it very difficult to control the i-limb digits device.

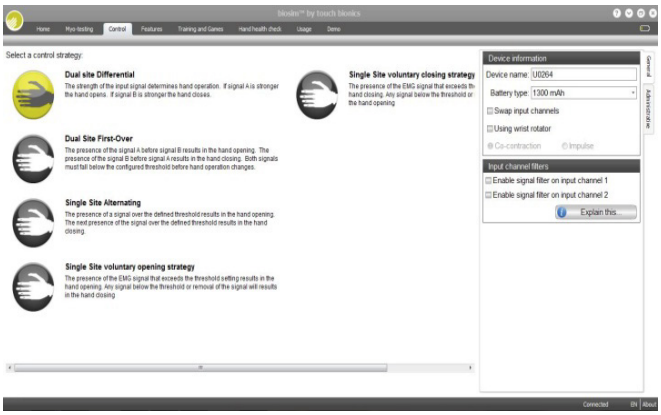
- If the gain in electrodes is set too high, the electrode may pick up extraneous noise signals and transmit them to the hand, causing unintentional operations of the hand. Also, the window to achieve proportional control is narrowed significantly and makes it very difficult to achieve slower precise movements.

- If the gain is set too low, then the user may complain that it is too difficult to operate.

The optimal electrode sites are where the user is able to generate the greatest difference between the two electrodes. The user must be able to separate the signals.

3.3.2 Control Strategy

The control page provides access to control strategy settings. Control strategy is the method by which the i-limb digits device responds to the input signals. While superior control of i-limb digits is possible with a dual site strategy, it is possible to control i-limb digits with a single electrode or FSR when a second site is not possible. Control strategy can only be changed through biosim; further control strategies for both dual and single site control are possible:



- Dual site Differential – the stronger of the two signals determines whether the hand opens or closes. As one signal becomes stronger than the other the hand direction changes. This strategy allows for rapid switching between hand operations, there is no requirement to fully relax the signals to change direction.

- Dual site First Over – the presence of a signal above the threshold level before its opposing signal will result in the hand moving in the direction of the signal. While the first over signal remains above the threshold it will have dominance over the opposing signal – regardless of which is strongest. Signal dominance only changes once both signals drop below the threshold level. This is a useful training strategy to develop signal separation.

- Single site Alternating – the presence of a signal above the pre-set threshold level results in the hand opening. The next signal above the threshold level will result in the hand closing.

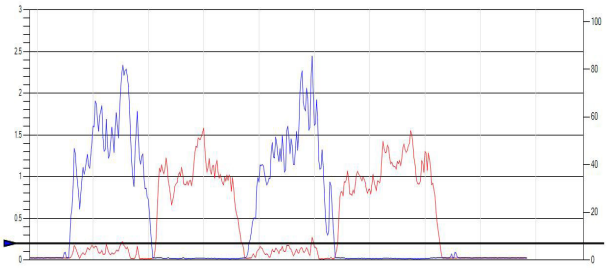
- Re-grip time-out is used to allow for a margin of error when the individual is moving in one direction and relaxes but does not yet want the hand to move in the opposite direction.

- Auto-revert is the time after which the hand will automatically revert to a close signal regardless of whether or not the next alternating signal would have been open. This prevents the user from dropping an item when they do not recall which signal was the most recent.

- Single site Voluntary Close – the presence of a signal above the pre-set threshold level results in the hand closing. Any signal below the threshold or removal of the signal will result in the hand opening.

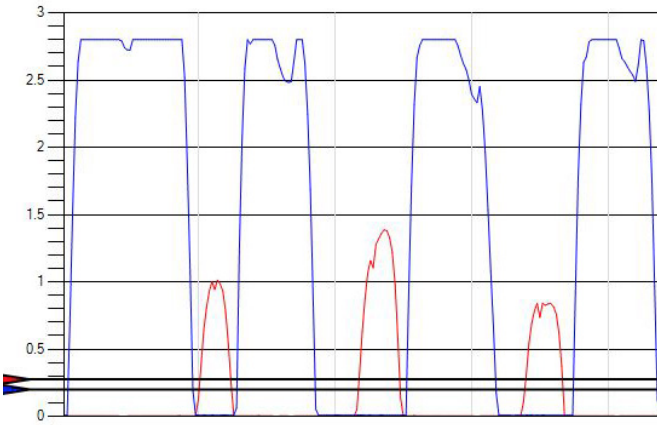
- Single site Voluntary Open – the presence of a signal above the pre-set threshold level results in the hand opening. Any signal below the threshold or removal of the signal will result in the hand closing.

1 The graph shows good separation of inputs.



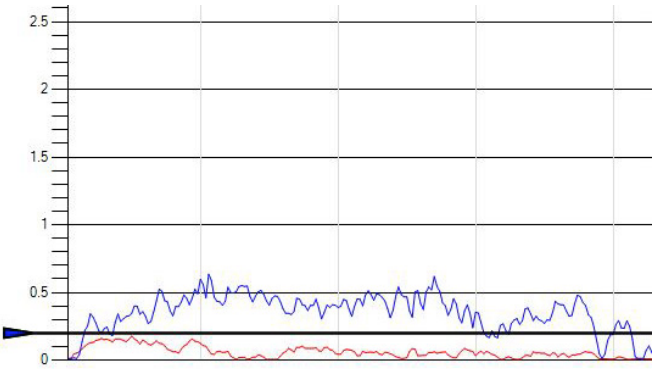
2 Graph showing good separation between input signals, however the blue, closing signal is flat lining at the top of the graph – proportional control of the hand is diminished.

Reduce the gain setting on closing input.



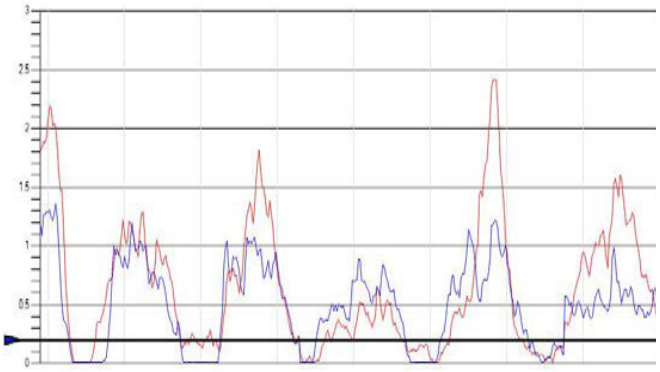
3 Graph showing low signal strength.

Encourage patient to increase signal strength, increase electrode gain if the patient is unable.



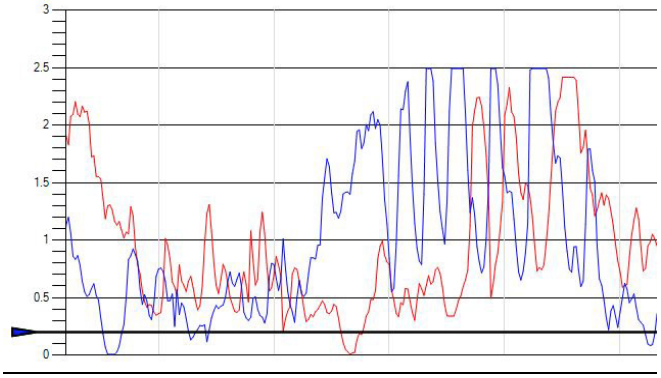
4 Poor signal separation with both signals being activated together.

Select first over control strategy to encourage the patient to activate one muscle group at a time. Ensure commands are clear and the patient understands what is required and return to basic control site training.



5 Excessive signal activity with both signals together.

Consider looking for alternative control sites, if the current control sites are the best option then select a first over control strategy, encourage the patient to relax signals and make definite open and closed actions with relaxation of the opposing muscles.



In the General tab of the control screen the Device information box will indicate the i-limb digits serial number. An option exists to swap input channels if the prosthesis digits are moving in the opposite direction; and to enter battery type.

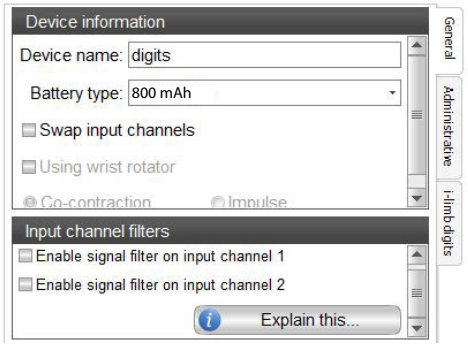


Figure 5

The polarity of individual digits can be changed using biosim. This feature can be found in the control tab (fig. 5).

In addition, the start of each digit can be delayed to achieve a more natural grip thus overcoming any mechanical alignment issues.

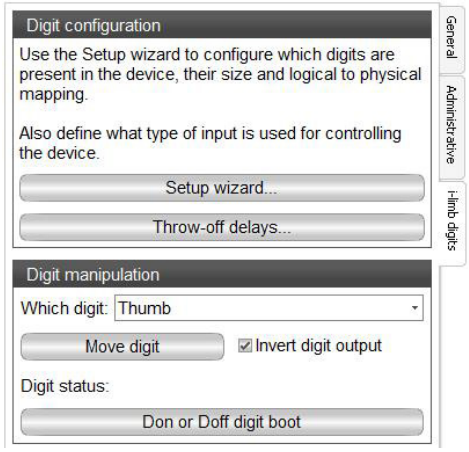

Digit configuration
Use the Setup wizard to configure which digits are present in the device, their size and logical to physical mapping.
Also define what type of input is used for controlling the device.
Setup wizard...
Throw-off delays...
Digit manipulation
Which digit: Thumb
Move digit
Invert digit output
Digit status:
Don or Doff digit boot
General
Administrative
i-limb digits

Figure 6

The administrative tab (fig.6) allows for the addition of personal information, the Patient Summary highlights user name and identifier code. The session management allows for the saving of the last training session and review of previous sessions.

Session management provides an option to save the last settings of the device. Setting can then be reloaded and reviewed using the relevant icons. There is also an option to return the device to factory defaults.

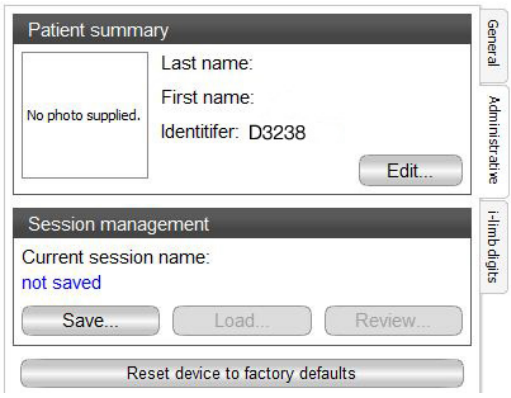
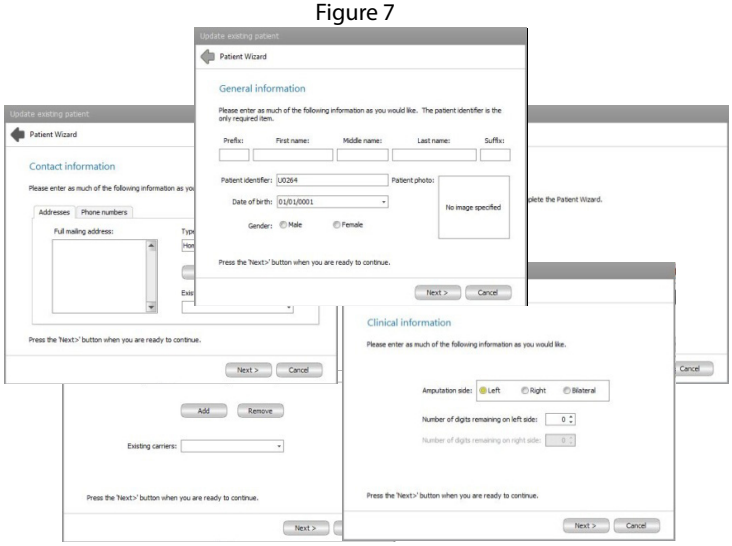


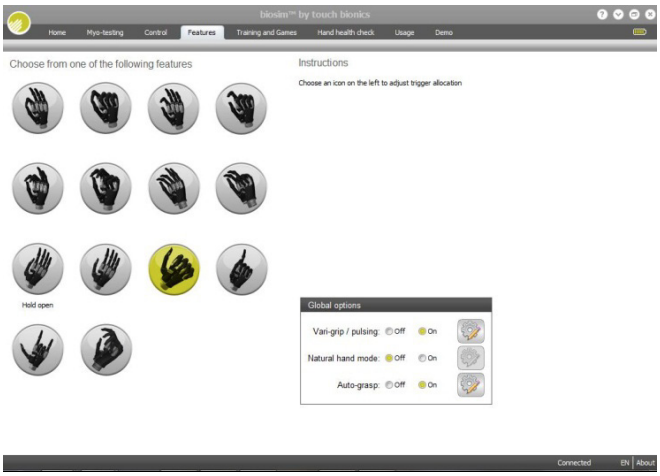
Figure 7

The Edit tab will lead to the Patient Wizard, allowing for more detailed personal information (fig. 7).



3.3.3 Features

Click on the features icon to enter the features suite. The feature page provides access to all available features and associated changes. Features are the actual movements of the hand and triggers are the muscle action used to create the movements.



The grip patterns illustrated are:

First row – 4 precision pinch options

Second row – 4 tripod grip options

Third row – 2 thumb park options, lateral grip and index point options

Fourth row – custom gesture and custom grip options

Features Catalogue

Precision Pinch Grip Options

Standard Precision Pinch Opened
middle, ring and little finger remain fully opened and switch off. Index finger and thumb provide grip.

Standard Precision Pinch Closed
middle, ring and little finger automatically close and switch off. Index finger and thumb provide grip.

Thumb Precision Pinch Opened
middle, ring and little finger remain fully opened and switch off. Thumb automatically moves to a partially closed position. Index finger will move to provide grip against a fixed thumb.

Thumb Precision Pinch Closed
middle, ring and little finger automatically close and switch off. Thumb automatically moves to a partially closed position. Index finger will move to provide grip against a fixed thumb.

Tripod Grip Options

Standard 3 Jaw Chuck (Tripod) Opened
ring and little finger remain fully opened and switch off. Thumb, index and middle fingers move to provide grip.

Standard 3 Jaw Chuck (Tripod) Closed
ring and little finger move to terminal close. Thumb, index and middle fingers move to provide grip.

Thumb 3 Jaw Chuck (Tripod) Opened
ring and little finger remain fully opened and switch off. Thumb automatically moves to a partially closed position. Index and middle fingers move to provide grip against a fixed thumb.

Thumb 3 Jaw Chuck (Tripod) Closed
ring and little finger move to terminal close. Thumb automatically moves to a partially closed position. Index and middle fingers move to provide grip against a fixed thumb.

Additional Grip and Gesture Options

Thumb Park Continuous – all four fingers remain open and switch off, only the thumb will move.

Thumb Park Quick – all four fingers remain open and switch off, for 1.5 seconds the thumb will close and then automatically return to an open position.

Lateral Grip – all four fingers fully close and switch off. Only thumb will move.

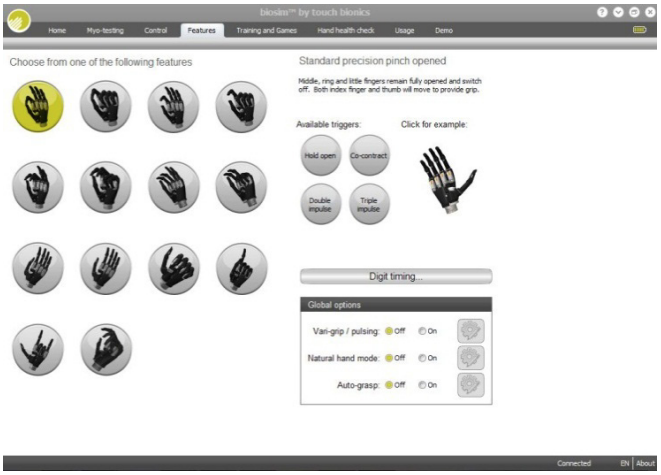
Index Point – thumb, little, ring and middle fingers close and switch off. Only the index finger will move.

Custom Gesture – all fingers automatically move to a user defined fully opened and fully closed position.

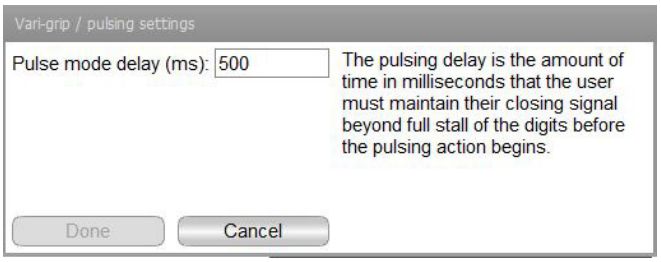
Custom Grip – all fingers automatically move to a user defined position.

Additional Functioning

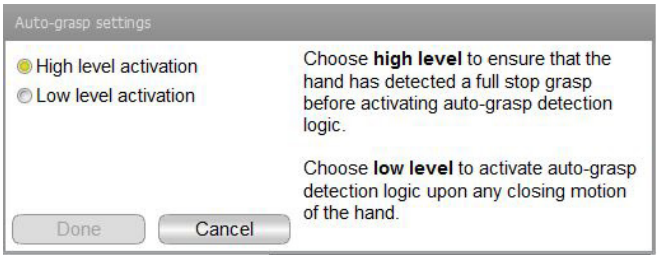
Toward the bottom right of the screen the additional Global Options box can be used to give access to Vari-grip / pulsating, Natural Hand and auto-grasp modes.



1. Vari-grip / pulsating: this mode provides additional grip force with subsequent activation of the closed signal. The default setting for activation is 500ms (0.5 seconds) which can be customized between 250ms (0.25 seconds) to 3,000ms (3 seconds).


Vari-grip / pulsing settings
Pulse mode delay (ms): 500
The pulsing delay is the amount of time in milliseconds that the user must maintain their closing signal beyond full stall of the digits before the pulsing action begins.
Done
Cancel

2. Auto-grasp: this feature enables the user to counter a false open signal during grasping. If a false open signal is identified the grip of the hand is automatically closed around the object. The option of High level activation ensure that the device has detected a full stop grasp before activating auto-grasp. Low level activation creates auto-grasp upon any closed signal to the device.

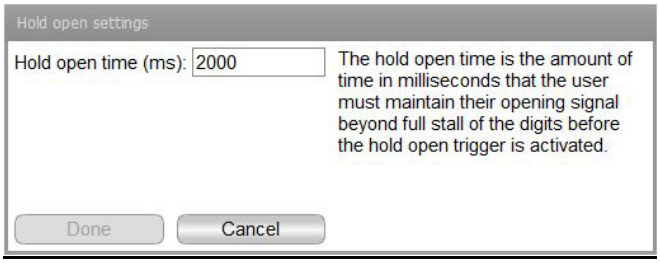

Auto-grasp settings
High level activation
Low level activation
Choose high level to ensure that the hand has detected a full stop grasp before activating auto-grasp detection logic.
Choose low level to activate auto-grasp detection logic upon any closing motion of the hand.
Done
Cancel

Both of these modes can be completely turned off.

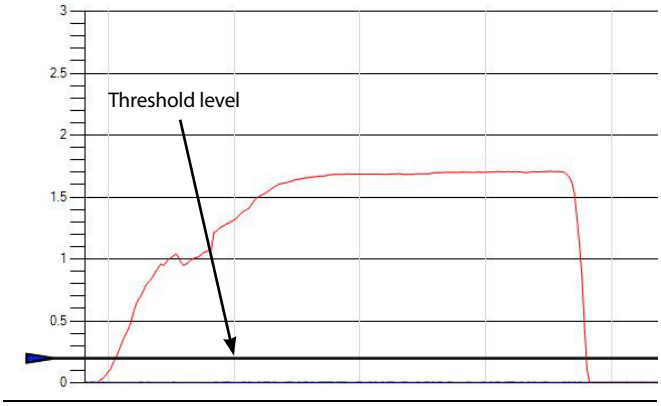
Triggers

A trigger is the stimulus sensed by the electrodes or FSR. Four potential triggers are available, Hold open, Co-contraction, Double impulse and Triple impulse.

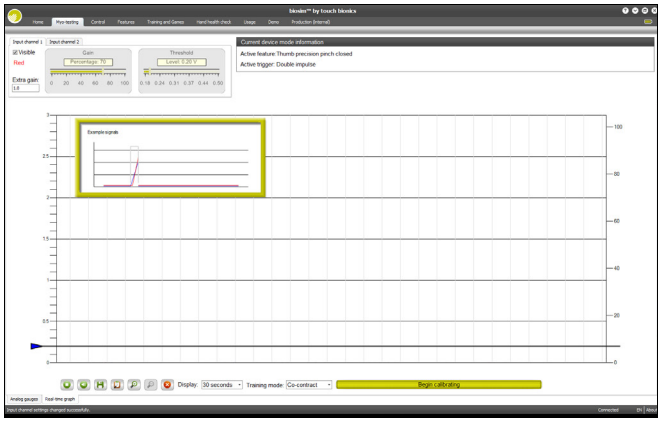
1. **Hold open** (a prolonged open signal), this is preset to 2,000ms (2 seconds) and can be customized from 2,000 to 5,000ms.

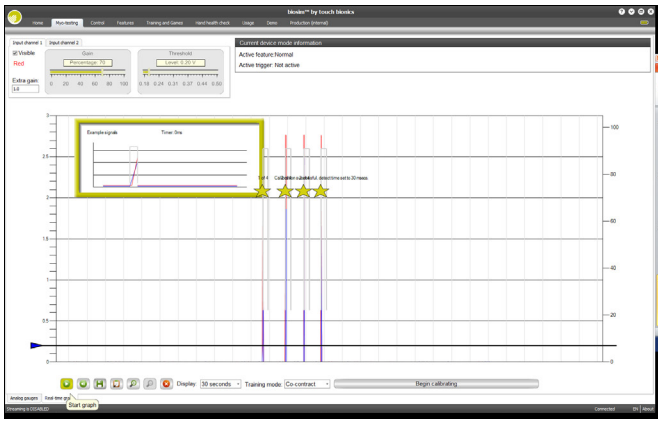

Hold open settings
Hold open time (ms): 2000
The hold open time is the amount of time in milliseconds that the user must maintain their opening signal beyond full stall of the digits before the hold open trigger is activated.
Done
Cancel

The graphs shows a good hold open trigger, the signal strength is well above 1.0V and the signal duration is around 3 seconds.

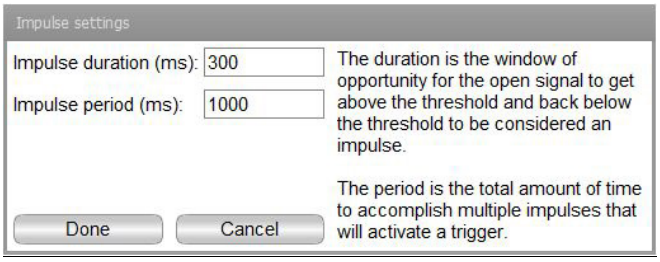


2 **Co-contraction** is the creation of simultaneous open and closed signals. Co-contraction may be customized if a patient has difficulty with activation within the default time. This is done by going to myo-testing and entering co-contraction in the training mode drop down box. The “Begin Calibrating” icon will then appear, on starting calibration 4 successful attempts must be made at a co-contraction for biosim to create the parameter settings.



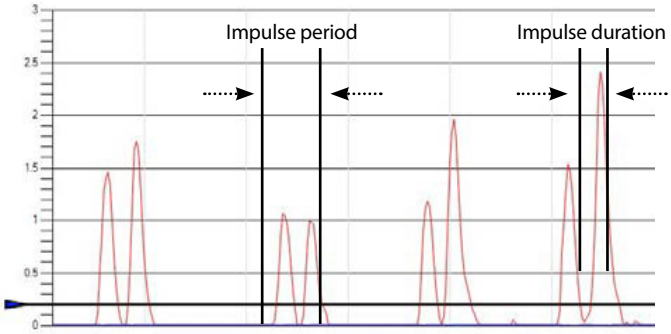


3 **Double impulse** (two open signals separated by relaxation beneath the threshold) the ***impulse duration*** is the period of time that the impulse is above the threshold. It is preset at 300ms and can be customized from 30 to 3,000ms. The ***impulse period***, or period within which both impulses must be completed to be recognized, is preset at 1,000ms and can be customized from 500 to 3,000ms.


Impulse settings
Impulse duration (ms): 300
Impulse period (ms): 1000
The duration is the window of opportunity for the open signal to get above the threshold and back below the threshold to be considered an impulse.
The period is the total amount of time to accomplish multiple impulses that will activate a trigger.
Done
Cancel

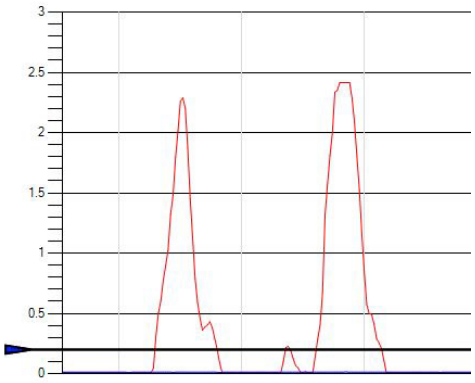
N.B. The hand must be fully open for the Double Impulse trigger to be recognized.

The graph shows an optimal double impulse. Both impulses are of sufficient strength to break the threshold, the first impulse drops below the threshold to allow recognition of the second impulse. Both impulses are activated within the preset impulse period.



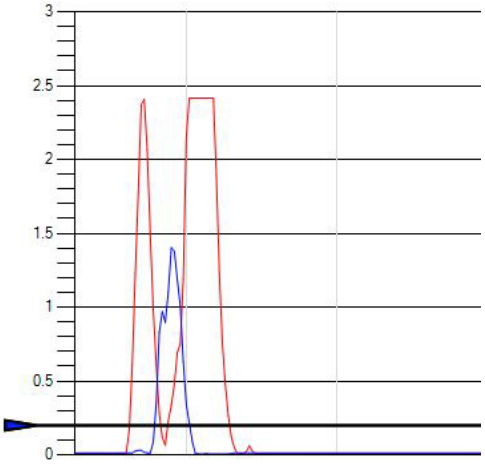
(i) The graph shows a failed double impulse attempt. The impulse signals are sufficiently strong, however the impulses are too far apart to be identified. Both impulses are recognized as individual open signals.

Encourage the patient to perform the impulses close together. Consider lengthening the impulse period.



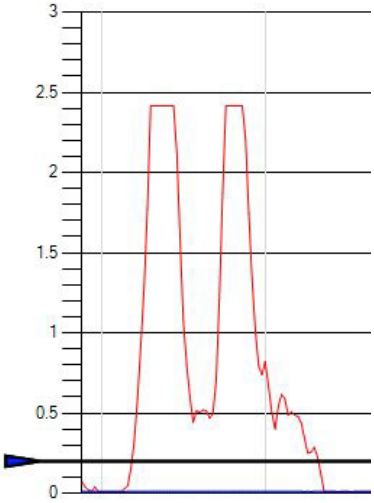
(ii) The graph shows a failed double impulse attempt. The double open signals are strong and within the preset impulse period, however the presence of the blue, closed signal disrupts the impulses.

Encourage the patient to relax the closed signal during double impulse activation. Consider changes to gain and threshold of the closed channel, depending on activation during other activities. Consider a first over strategy – the signal would be accepted using this strategy.

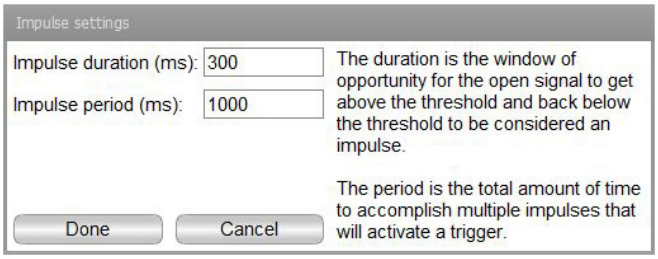


(iii) The graph shows a failed double impulse attempt, using dual site differential. The two open signals are sufficiently strong, however there is no relaxation between impulses. The signal is recognized as one open signal.

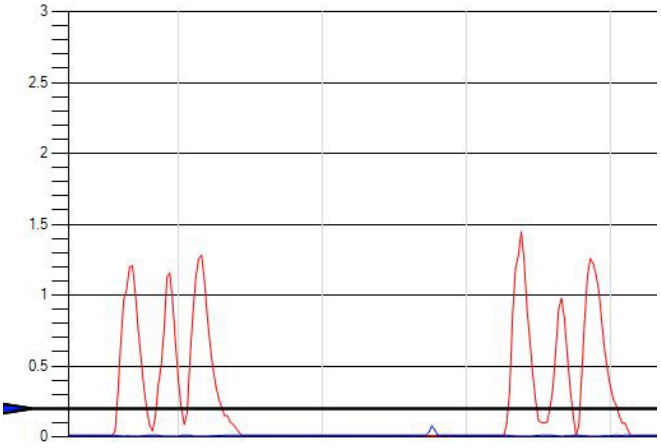
Encourage the patient to relax inbetween impulses.



4 **Triple impulse** (three open signals separated by relaxation beneath the threshold) settings are the same as with the Double impulse trigger. The impulse duration is preset at 300ms and can be customized from 30 to 3,000ms. The impulse period is preset at 1,000ms (1 second) and can be customized from 500 to 3,000ms.


Impulse settings
Impulse duration (ms): 300
Impulse period (ms): 1000
The duration is the window of opportunity for the open signal to get above the threshold and back below the threshold to be considered an impulse.
The period is the total amount of time to accomplish multiple impulses that will activate a trigger.
Done
Cancel

The graph shows an optimal triple impulse. In a similar manner to the double impulse, the three impulses are of sufficient strength to break the threshold. The first and second impulses drop below the threshold to allow recognition to subsequent impulses. All three impulses are activated within the preset impulse period (impulse period is not indicated on the graph).

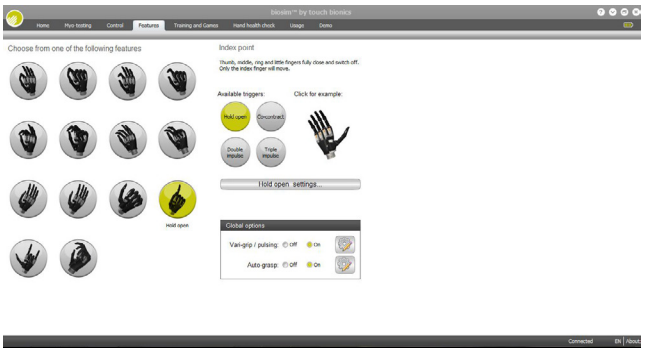


N.B. The hand must be fully opened for the Triple Impulse trigger to be recognized.

Once the trigger is linked to a feature the settings tab appears, providing the option to make changes to timings. In addition the feature is now labeled with the relevent trigger. Any of the above four potential triggers can be linked with any of the above features. Some users are able to perform activities of daily life (ADL's) without the use of any triggers. In many cases users initially set one or two triggers while familiarity and control is gained.

Linking Triggers with Features

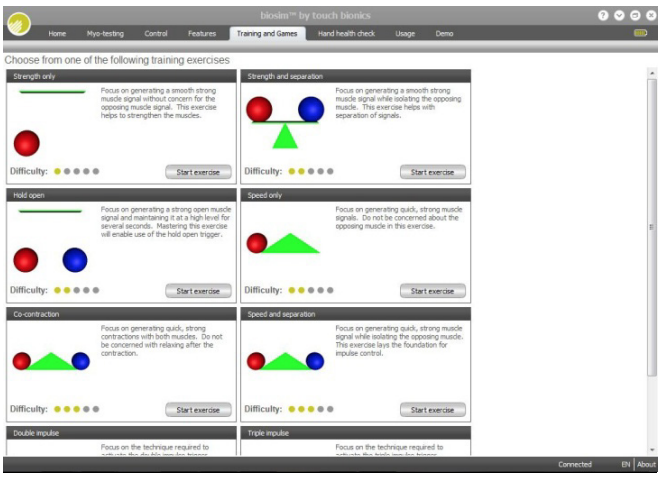
In order to link a trigger with a feature simply click on to the desired feature, the feature will now be highlighted. Select and click the desired trigger which has been selected to link with the highlighted feature. Both feature and trigger should now be highlighted and the descriptive label will now appear under the feature icon. The illustration indicates the Index Point Feature linked to the Hold Open Trigger.



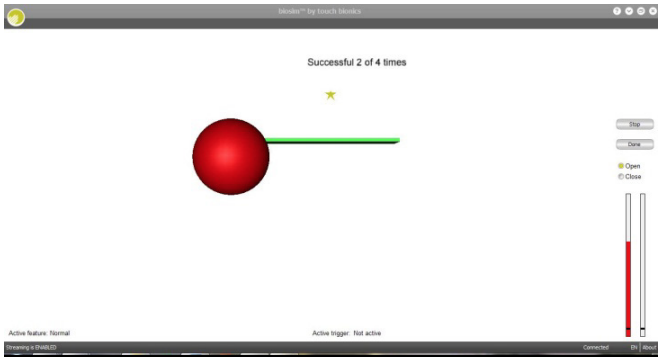
By left clicking any of the features on the features page the available triggers and example sections will also appear. In order to preview a feature simply highlight the feature and click on example to the right of the screen. The section will then enlarge and provide a demonstration of the feature. The hand Image can be rotated to improve visualization by holding the left mouse key and moving the curser in the direction of the intended rotation.

3.3.4 Training

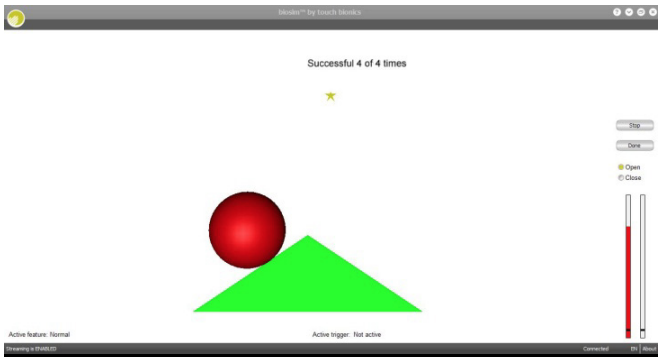
The training suite contains a variety of short training exercises aimed at developing control of the i-limb digits device. The opening screen highlights the series of exercises which can be selected individually and in any order. Practice both open and closed signals by selecting the appropriate box to the right. Click on "Start" to start the exercise and "Done" when the exercise is complete. An indication of difficulty is provided by the 5 point scale on each module.



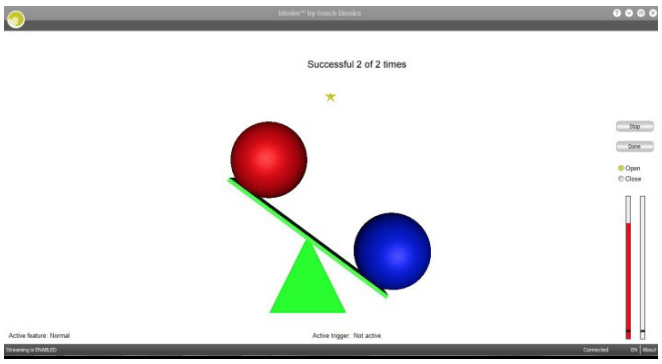
Strength Only focuses on generating a smooth strong muscle signal without concern for the opposing muscle signal. This exercise helps to strengthen the muscles.



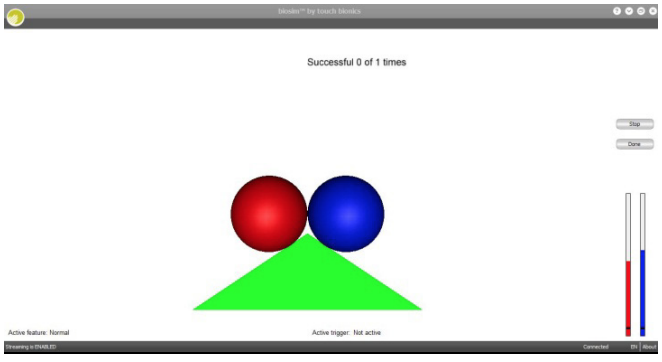
Speed Only focuses on generating quick, strong muscle signals. Do not be concerned about the opposing muscle in this exercise.



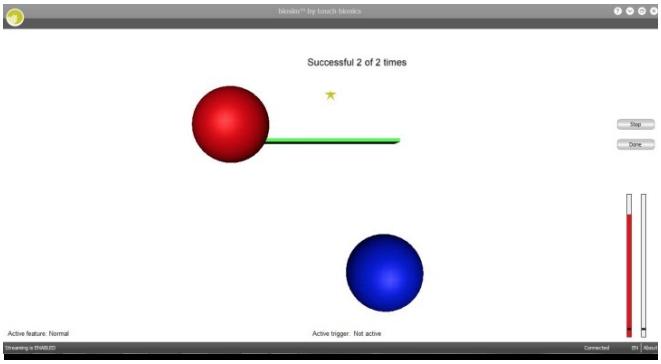
Strength and Separation focuses on generating a smooth, strong muscle signal while isolating the opposing muscle. This exercise helps with separation of signals.



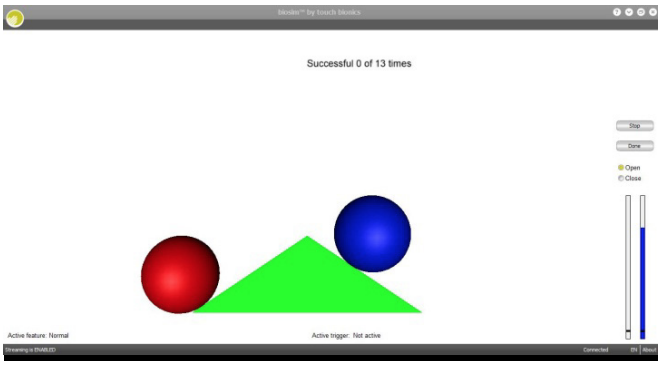
Co-contraction focuses on generating quick, strong simultaneous contractions with both muscles. Do not be concerned with relaxing after the contraction.



Hold Open focuses on generating a strong open muscle signal and maintaining it at a high level for several seconds. Mastering this exercise will enable use of the hold open trigger.



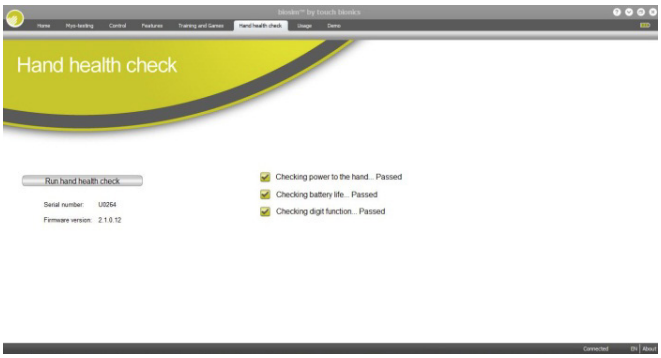
Speed and Separation focuses on generating quick, strong muscle signals while isolating the opposing muscle. This exercise lays the foundation for impulse control.



3.3.5 Hand Health Check

Hand Health Check screen provides a quick and easy check of the hand. Click on the "Run Hand Health Check" icon and the health check will begin. There must be an internet connection to run the Hand Health Check.

The i-limb digits device will then go through a series of movements as each digit is checked, the process will run for approximately 8 seconds and provide basic feedback on each step.



3.3.6 Usage

The Usage suite provides information on various measures of usage, including power cycles (the number of times the hand has been switched on), open / close cycle and actual feature used.

Feature count gives the number of times the open and closed command has been used with in a specific grip pattern.

Excessive Signal Activity Count gives the number of times the user maintained a signal above the threshold level for more than 3 seconds.

Options to refresh and reset, along with saving and illustrating the data are also provided (fig.8).

This analysis is very useful when reviewing usage and reliance on the various features of the i-limb digits device.

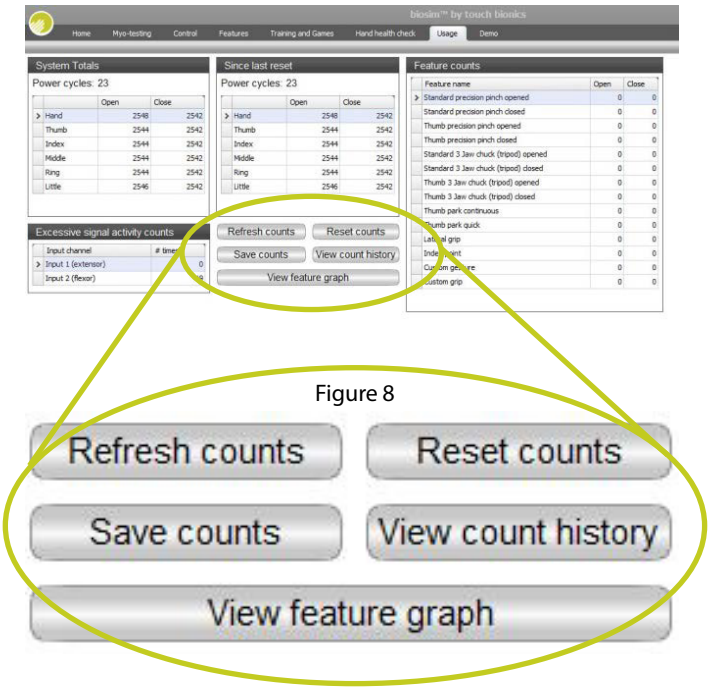


Figure 8

3.3.7 Exit

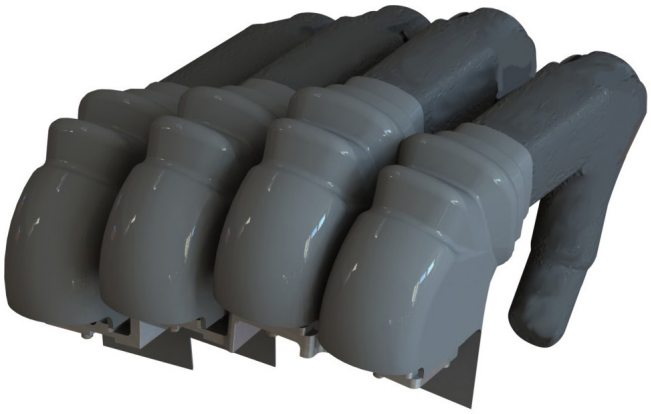
Use the Exit icon to fully exit biosim.

4.0 Coverings

4.1 Cover Options

Silicone digit knuckle covers and tips will be provided for the i-limb digits device. Digit covers will be ready to fit and designed to cover each digit.

Touch Bionics' approved digit covers must be used with each digit of the device. The warranty will become void if the device is used without an approved cover. Refer to the i-limb digits component assembly guide (MA01073) for instructions on how to properly attach the digit cover assembly.



General Precautions

- The i-limb digits device must be used with approved Touch Bionics' digits covers.
- Never put more than one cover on each digit of the i-limb digits device.
- Always use the digits cover designed for the i-limb digits device.
- Ensure covers are fitted properly.

i-limb digits covers do not provide full protection from moisture, oil, dust and dirt ingress. Caution should be observed.

5.0 Adjustments

5.1 Adjustments

For all information surrounding assembly or replacement of digits, thumb or associated components refer to i-limb digits Component Assembly Guide (MA01073).

6.0 Support Information

6.1 i-limb digits with Full Forearm Socket

In certain circumstances it will not be possible to create an i-limb digits device with Wristband for a patient who fits the initial selection, refer to Section 1.3. These reasons may be because of:

1. A lack of availability, or inadequate control sites within the hand.
2. The suspension cannot be achieved from a hand only socket

In such circumstances an i-limb digits device with full forearm socket can be fitted.

A device utilizing a full forearm socket will be compatible with many of the i-limb digits components. However, a number of differences will need to be appreciated:

1. Batteries will be fabricated into the forearm socket and will be different from batteries which are used with the Wristband outlined within this manual. Available batteries are 1,300mAh or 2,000mAh. An alternative battery charger will also be provided.
2. PCB will be separate and will require fabrication within the forearm socket.
3. Touch Bionics' Standard Electrodes should be used.
4. Wiring harnesses will also match the alternative battery and PCB components.

A forearm socket would typically extend to approximately mid forearm. A pouch within the silicone socket can be created to locate the componentry (batteries, PCB, etc). This pouch can be positioned according to the requirements of the patient, often on the medial aspect of the forearm. Consideration should be given in the design of the socket to suspension, fastenings (zippers, straps, etc) and donning/doffing.

When using a forearm socket some of the benefits of the i-limb digits device with Wristband will be lost. In particular, the enhanced range of motion at the wrist; open forearm design and easily accessible batteries for ease of charging.

During socket fabrication, appropriate measures must be taken to prevent sweat entering into the battery connector, which may result in a short circuit and compromise use of device. Conventional sweat prevention measures should be adopted.

6.2 Troubleshooting

Problem	Action
Prosthesis does not operate	Ensure the prosthesis is switched on Ensure the battery is connected Ensure the battery is charged Check that electrodes or FSR's have good contact Check that the Standard Electrode cable is installed correctly
One digit does not operate	Exchange with an alternative working digit and re-check. Then contact Touch Bionics Check if the digit operates correctly using the Hand Health check in biosim
Prosthesis stops halfway through an action	Check the battery cable is not damaged Check that the i-limb digits screws are not loose Check the electrode cable is not damaged Electrode gain settings may be too high or too low
User complains that the prosthesis is hard to operate	Ensure the battery has good charge Ensure that electrodes or FSR's have good contact Ensure the electrodes are well grounded Ensure good electrode or FSR placement and wiring Check electrode settings
Battery charge does not last a full day	Fully charge the battery, this may take up to 2 hours Check the battery connection Ensure electrodes are not set above 5.5 Check user is not holding a sustained signal to the hand and check biosim user statistics Replace with a spare i-limb digits battery
Prosthesis opens when a close signal is provided	Switch the open and closed channels via biosim
Battery is not working	Check the battery is connected Check the battery is charged Check the device using one of the spare i-limb digits batteries

6.3 Warnings and Precautions

i-limb digits device

Do not use without an approved cover

Do not use under water

Do not use to operate heavy / industrial machinery

Do not use with machinery with moving parts that may cause personal injury or damage

Users must comply with local regulations on the operation of automobiles, aircraft, sailing vessels of any kind and any other motorized vehicle or device

Do not use for extreme activities that may cause injury to a natural hand

Do not expose to excessive moisture, liquid, dust, vibration or shock

Do not expose to high temperatures

Do not expose to naked flames

Do not use or expose to explosive atmospheres

Do not disassemble componentry or modify in any way

Maintenance, repairs and upgrades may only be performed by qualified Touch Bionics technicians and technical partners

Do not use with a damaged cover

Damaged covers must be replaced or repaired by a qualified Touch Bionics technician or technical partner

Only approved Touch Bionics accessories and tooling may be used with the i-limb digits device

Do not use an i-limb device to operate your mobile device whilst it is connected to a mains outlet, as this can affect EMG signal.

Batteries

Do not bend or exert excessive pressure on the battery

Do not pierce the battery

Do not disassemble

Do not expose to high temperatures

Do not incinerate batteries

Do not alter battery terminal wires

Do not short circuit the battery

Do not store batteries inside a vehicle

Dispose of batteries in accordance with US, European or local regulations

Only use the appropriate Touch Bionics charger to charge Touch Bionics batteries

If the battery has visibly ballooned or swelled:

- discontinue the charging process immediately
- disconnect the battery
- remove to a safe area
- leave and observe for 15 minutes
- replace with new battery
- do not re-use
- dispose of any faulty batteries in an appropriate manner

Before each use of the device, please inspect for evidence of wear and tear or damage. If wear and tear or damage is noticed, remove device immediately, and contact Customer Support.

Failure to comply with the above guidelines will invalidate the warranty.

If you experience technical problems with the i-limb digits device call Touch Bionics as follows:

North American Customers
(Canada, Mexico & US)
Tel:+1 855 MYiLIMB (694 5462)
UK & Non-North American Customers
Tel: +44 1506 438 556

Driving of Motor Vehicles

The i-limb device has the functional capability to assist a patient with driving a motor vehicle however due to factors including the differences in world-wide driving regulations and the variations in the level of ability between patients Touch Bionics is unable to provide definitive advice in respect of a patient with an i-limb device driving a motor vehicle.

Touch Bionics is aware that patients have used the i-limb to drive a motor vehicle and our recommendations prior to a patient doing so would include the following:-

- contacting the driving authority in your home location to obtain and understand the local regulations;
- working with the appropriate authorities to have your car modified to meet the local regulations for your respective disabilities as required;
- re-taking any mandatory driving test using your i-limb device to demonstrate your ability to operate a motor vehicle safely if required by local regulations;
- contacting your insurance provider and advise them that you will be using the i-limb device to drive a motor vehicle;
- ensuring that the device has a fully charged battery. Please note that the i-limb battery will show a low battery signal which will alert you if the battery requires to be charged;
- switching off the i-limb device. This is due to the possibility of involuntary muscle signals being generated; and
- moving the thumb into the lateral position to allow the i-limb to be removed from the steering wheel without opening the hand.

It is entirely the patient's responsibility to seek confirmation that they are physically and legally able to drive using the device and to the fullest extent permitted by law Touch Bionics shall under no circumstances whatsoever be liable to the patient or any other party as a result of or in connection with a patient with an i-limb device driving a motor vehicle.

7.0 User Information

7.1 User Details

Provision of the following basic information will enable easy identification if the prosthesis is returned to customer service. Please forward details to Touch Bionics as per the contact information on the back page of the manual.

User Name:

Fitting Date:

Device Purchase Date:

Device Serial Number:

It is recommended that the above information is also included in the patient notes.

8.0 Appendix

8.1 Technical Information

i-limb digits	
Voltage	7.4 V (nominal)
Max. Current	5 A
Battery Capacity	800 mAh capacity
Push up from wheelchair: 4 digits	80Kg/176lbs
Push up with one digit	20Kg/44lbs
Carry heavy bag 4 digits	100Kg/220lbs
Carry heavy bag one digit	25Kg/55lbs
Carry heavy bag on thumb	25Kg/55lbs

8.2 i-limb digits Information

Hazardous Area Classification	
The i-limb digits device is not intended for use outside the boundaries of the environments listed below. The customer or user of the i-limb digits device should assure that it it not used in such environments	
Condition	Level
Maximum temperature	+70˚c
Minimum temperature	-40˚c
Hazardous Area Classification	Non Hazardous

8.3 Component Compatibility

8.3.1 EMC and Electrical Information

Please refer to www.touchbionics.com/downloads/document-library for Electro Magnetic Compatibility (EMC) and Electrical Information for i-limb products.

8.4 Warranty

Refer to www.touchbionics.com/downloads/document-library to review warranty information.

	Refer to operating instructions
	Class II equipment – provides double Isolation to protect against electric shock
IP40	Degree of protection – IP40 Protection against penetration by solid particles with diameters larger than 1 mm. No special protection against penetration by water
	Batch/Lot/ID Number
	For i-limb digits devices: The unique serial number for i-limb digits devices is a D with a 4 digit alpha / numeric number.
	WEEE Compliance
	Catalogue number
	Manufacturer/Date of Manufacture
	European Conformity

Customer Service/Contact Information:

Touch Bionics, Unit 3 Ashwood Court,
Oakbank Park Way, Livingston EH53 0TH, UK

Tel: Customer Service: +44 (0) 1506 438 556

www.touchbionics.com

Touch Bionics, 35 Hampden Road
Mansfield MA 02048, USA

Tel: +1 855 MY iLIMB (694 5462)

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For address details and further information
please visit www.touchbionics.com

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